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PTO 1390 Page 1 of 1 | US Dept. of Commerce Pat. & Trademark Office | Attorney's Docket No. 21927

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 USC 371

US. Application No. (if known) 09/890372

INTERNATIONAL APP. NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/00444	21 January 2000	28 January 1999

TITLE OF INVENTION

DEVICE FOR SHRINKING A SHRINK-WRAP FILM

APPLICANT(S) FOR DO/EO/US

Reiner HANNEN et al

Applicant herewith submits to the United States Designated/Elected Office (DO/EU/US) the following .

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 USC 371.
2. ■ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371.
3. ☐ This is an express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 317(b) and PCT Articles 22 and 39(1).
4. ■ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 USC 371(c)(2)).
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau.
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Patent Office.
6. ☐ A translation of the International application into English.
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau.
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3).
9. ■ An oath or declaration of the inventor(s) (35 USC 371(c)(4).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).

Items 11. to 16. below concern documents or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ■ An Assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ■ Other items of information.

US Application no (if known)	International Application no.	Attorney's Docket No.
09/890372	PCT/EP00/00444	21927

17. The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5):		
Search report has been prepared by the EPO or JP $860.00		
Int'l prel. exam. fee paid to USPTO (37 CFR 1.482) $690.00		
No int'l prel. exam. fee paid to USPTO (37 CFR 1.482) but int'l search fee paid to USPTO (37 CFR 1.445(a)(2) $710.00		
Neither int'l prel. exam fee (37 CFR 1.482) nor int'l search fee (37 CFR 1.455(a)(2)) paid to USPTO $1000.00		
Intl. prel. exam. fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Art. 33(2-4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT		
Surcharge of $130.00 for furnishing oath or declaration later than ☐ 20 ■ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	**$65**	

CLAIMS	NO. FILED	NO. EXTRA	RATE		
Total claims					
Ind. claims					
MULTIPLE DEP. CLAIM(S) (if applicable) **(see prel. amt.)**					

TOTAL OF ABOVE CALCULATIONS	**$130**	
Reduction of ½ for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (37 CFR 1.2, 1.27, 1.28)	**$65**	
SUBTOTAL	**$65**	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		
TOTAL NATIONAL FEE	**$65**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The Assignment may be accompanied by an appropriate PTO-1595 cover sheet (37 CFR 3.28, 3.39)	**$40**	
TOTAL FEES ENCLOSED	**$105**	
	Amt to be refunded	
	Amt to be charged	

a. ☐ A check in the amount of to cover the above fees is enclosed
b. ☐ Please charge my deposit account 18-2025 **$00.00** to cover the above fees. A copy of this sheet is enclosed.
c. ■ Please charge the amount due to the credit card identified in the attached PTO-2038.
d. ■ The commissioner is authorized to charge any additional fees which may be required or credit any overpayment to deposit account 18-2025. A copy of this sheet is enclosed
e. ■ A PTO-2038 in the amount of **$40** to cover recordal of the Assignment is enclosed

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:

The Firm of Karl F. Ross P.C.
5676 Riverdale Ave. Box 900
Riverdale (Bronx), NY 10471

Herbert Dubno, Reg. No. 19,752

21927

CERTIFICATE OF EXPRESS OR FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, or as Express Mail if the number of the Express Mail mailing label is provided below, in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on SEP 13 2001 (Date of Deposit)

EL842185585US Express Mail Label Number

Signature

The Firm of Karl F. Ross, P.C.

IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor	**Reiner HANNEN et al**
Patent App.	**09/890,372 (US Nat'l phase of PCT/EP00/00444)**
Filed	**26 July 2001**
For	**DEVICE FOR SHRINKING A SHRINK-WRAP FILM**

Hon. Commissioner of Patents
Washington, DC 20231

RECORD OF TRANSMITTAL--PCT APPLICATION

- ■ PCT Transmittal
- □ PCT Application
- □ Translation
- □ Sheets of Drawing (0)
- ■ PCT Declaration
- □ PCT Documents
- □ International Search Report
- □ Preliminary Amendment
- ■ Assignment (with PTO-1595 and sep. PTO-2038)
- ■ PTO-2038 for Official Fees
  - ■ Late filing $65.00

Total **$65.00**

Please charge any fees not covered by an enclosed PTO-2038 to account 18-2025 of the undersigned.

12 September 2001

Respectfully submitted,
The Firm of Karl F. Ross P.C.

5676 Riverdale Ave. Box 900
Bronx, NY 10471-0900
Tel: (718) 884-6600
Fax: (718) 601-1099
Customer No. 535
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Herbert Dubno, Reg. 19,752

U.S. APPLICATION NO.		FIRST NAMED APPLICANT		ATTY. DOCKET NO.
09/890372		HANNEN	R	21927

INTERNATIONAL APPLICATION NO.
PCT/EP00/00444

I.A. FILING DATE	PRIORITY DATE
21 JAN 00	28 JAN 99

HERBT DUBNO
THE FIRM OF KARL F ROSS
5676 RIVERDALE AVE
PO BOX 900
RIVERDALE, NY 10471

KARL F. ROSS

RECEIVED
AUG 29 2001
RECEIVED
N Y N Y

DATE MAILED: 27 AUG 2001

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☑ an Elected Office (37 CFR 1.495):

- ☑ U.S. Basic National Fee.
- ☑ Copy of the international application.
- ☐ Oath or Declaration of inventors(s).
- ☐ Copy of Article 19 amendments.
- ☑ Priority Document.
- ☑ The International Preliminary Examination Report in English and its Annexes, if any.
- ☑ Translation of Annexes to the International Preliminary Examination Report into English.
- ☑ Indication of Small Entity Status.
- ☑ Translation of the international application into English.
- ☐ Translation of Article 19 amendments into English.
- ☐ Other:

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee.
- ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
  - ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
- ☑ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
  - ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☑ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of $_____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes MUST be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.

7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation
☐ PTO-875 ☐ PCT/DO/EO/920

Winston M. Alvarado
Telephone: 703-305-6421

FORM PCT/DO/EO/905 (March 2001)

D-850

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I hereby certify that I have deposited this correspondence with the US Postal Service as First Class or, if a mailing label number is given below, as express mail addressed to Comm. of Patents, Washington, DC 20231 on the below-given date.

09/890372

SEP 13 2001

Date

EL842185585

Express mail label number

Signature

IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventors	Yoh-ichi MATSUMOTO et al
Patent Appl.	PCT/US99/11179
Filed	19 May 1999 (International filing date)
For	HUMANIZED ANTIBODIES THAT RECOGNIZE VEROTOXIN II AND CELL LINE PRODUCING SAME

THIRD PARTY PROTEST BY THE PUBLIC PURSUANT TO 37 CFR 1.291 AGAINST A PENDING PATENT APPLICATION

Now comes Protester TRUSTEES OF TUFTS COLLEGE of Medford, Massachusetts and files this third party protest pursuant to 37 CFR 1.291 against PCT/US99/11179 and any equivalent U.S. National Phase Application pending before the U.S. Patent and Trademark Office. It is noted from WO 99/59629 that Applicant claimed the benefit of the priority of provisional patent application 60/086,570 filed 20 May 1998 and designated the United States as one of the countries in which the national phase of PCT/US99/11179 might be entered. Thus Protester must take into consideration the possibility that a U.S. National Phase Application derived from PCT/US99/11179 is currently pending before the U.S. Patent and Trademark Office.

Concise Explanation of the Relevance of WO 98/20903

Protester believes that no patent should issue in the United States that is the equivalent of U.S. National Phase of PCT/US99/11179 in view of the Protestor's own WO 98/20903 published 22 May 1998, a copy of which is enclosed herewith. Protester notes that WO 98/20903 was derived from PCT/US97/20722 having an International filing date of 14 November 1997 and claiming the benefit of the priority of U.S. Patent Application Serial No. 08/749,704 filed 15 November 1996. WO 98/20903 is believed to be an effective reference as of 15 November 1996, the priority date of U.S. Patent Application Serial No. 08/749,704 pursuant to 35 USC 102(e)(1). See Uncertainty Concerning When Application Publications and Patents are Effective as References, Harold R. Brown III, Journal of the Patent and Trademark Office Society, Vol. 83, No. 2, pp 77 to 107 (February 2001).

Protester further believes that WO 98/20903 is evidence that subject matter disclosed and claimed in Applicant's WO 99/59629 and presumably in any equivalent pending U.S. Patent Application pending before the U.S. Patent and Trademark Office was known or used by others in this country before the invention thereof by Applicants within the meaning of 35 USC 102(a) and

that with respect to that subject matter Applicants should not be entitled to obtain a U.S. Patent whose claims cover said subject matter.

Protester's WO 98/20903 is directed to human monoclonal antibodies against hemolytic uremic syndrome and to a method of treating hemolytic uremic syndrome by administering the human monoclonal antibodies to an individual in need of treatment for this disease or in need of protection from this disease.

Preferably the human monoclonal antibodies are obtained by producing one or more human monoclonal antibodies which bind specifically to Shiga toxin or Shiga-like toxin, said human monoclonal antibodies which bind specifically to Shiga toxin or Shiga-like toxin obtained by the following steps:

(1) administering Shiga-like toxoid I or Shiga-like toxoid II as an antigen to a transgenic mouse having human genes and inducing an immune response in the transgenic mouse;

(2) isolating splenocytes from the transgenic mouse following an immune response by the transgenic mouse and fusing the splenocytes to mouse myeloma cells to obtain mouse hybridomas producing human monoclonal antibodies; and

(3) screening the human monoclonal antibodies to obtain the human monoclonal antibodies which bind specifically to Shiga toxin or Shiga-like toxin; and

The human monoclonal antibodies which bind specifically to Shiga toxin or Shiga-like toxin are then administered to the individual in a therapeutically effective amount.

A particularly preferred feature according to Protester's pending application which is the U.S. National Phase of PCT/US97/20722 is the use of a transgenic mouse to generate the human monoclonal antibodies which specificity against the Shiga-like toxins I and II. According to Applicants' WO 99/59629 on page 26, lines 15 to the bottom to page 27, line 5, obtaining human monoclonal antibodies against Verotoxin (Shiga) from transgenic animals, especially transgenic mice, is one feature of the invention. Protester strongly believes that no patent should issue in the U.S. National Phase of PCT/US99/11179 with claims directed to human monoclonal antibodies obtained from transgenic mice or to a method of treating toxic uremic syndrome by administering the human monoclonal antibodies to a patient with toxic uremic syndrome.

Protester notes the International Search Report attached to WO 99/59629 performed by Examiner Rodney Swartz of the U.S. Patent and Trademark Office on 8 July 1999. The search was an International Search and Examiner Swartz represented the International Searching Authority. Examiner Swartz found Protester's WO 98/20903 and stated that the document was published prior to the Applicants' international filing date of WO 99/59629, namely 19 May 1999 but after the Applicants' U.S priority date of 20 May 1998 and did not apply the reference against the claims. Protester strongly believes, however, that under 35 USC 102(e)(1) the claims of any related U.S. application belonging to Applicants that is equivalent to WO 99/59629 and that overlap with the claims of WO 99/59629 should be rejected in view of Protester's WO 98/20903.

Protester is including copies of WO 98/20903, WO 99/59629 and Uncertainty Concerning When Application Publications and Patents are Effective as References, Harold R. Brown III, Journal of the Patent and Trademark Office Society, Vol. 83, No. 2, pp 77 to 107 (February 2001). While Protester regards the entire WO 98/20903 to be relevant to the examination of any U.S. application belonging to Applicants that is equivalent to WO

99/59629, it is especially believed that page 3, lines 3 through 16, and Example 2 on pages 16 through 21 of WO 98/20903 are relevant. Example 2 describes the human monoclonal antibodies against Shiga-like toxins and how these human monoclonal antibodies were obtained by administering the proper immunogen to a mouse containing human genes (transgenic mouse). Page 26, lines 15 to the bottom and page 27, lines 1 through 5 of WO 99/59629 disclose an invention highly related to the disclosure in WO 98/20903.

Alternatively any related U.S. application belonging to Applicants that is equivalent to WO 99/59629 and that includes claims that overlap with the claims of WO 99/59629 should be rejected under 35 USC 102(a) in view of Protester's WO 98/20903. WO 98/20903 provides evidence that the invention claimed in WO 99/59629 was known or used by others in this country before the invention thereof by Applicants as required by that section of the Statute.

Protester is especially concerned with claim 22 of WO 99/59629 that is broad enough to cover a method of treating a patient with hemolytic uremic syndrome by administering human monoclonal antibodies to the patient human antibodies that bind

to Shiga-like toxins, including Shiga-like toxin I and Shiga-like toxin II. Protester believes that the first to invent such human monoclonal antibodies to Shiga-like toxins I and II are Saul Tzipori, Ramaswamy Balakrishnan, and Arthur Donohue-Rolfe, the inventors named in WO 98/20903. Protester is concerned that the Examiner may allow Applicants in a pending U.S. application equivalent to WO 99/59629, a claim of the scope of or overlapping with claim 22 of their WO 99/59629 covering administration of a human antibody, especially a human monoclonal antibody obtained from a transgenic mouse, to a patient suffering from or at risk of a verotoxin infection. Protester believes that under 35 USC 102(g) an issue of priority of invention will have developed between such a patent application and Protester's U.S. Patent Application Ser. No.09/302,125 filed 24 April 1999 which is a division of U.S. Patent Application Ser. No. 08/749,704 filed 15 November 1996, the priority of which was claimed in PCT/US 97/20722. In such a situation an interference between Protester's U.S. Patent Application Ser. No.09/302,125 and any such patent application belonging to Applicants should be declared.

There is antecedent basis in WO 98/20903 for every element of claim 22 of WO 99/59629.

Page 2, lines 29 to 35 of WO 98/20903 discloses a therapeutic method to treat hemolytic uremic syndrome by administering to an individual a therapeutically effective amount of monoclonal antibody which binds specifically to either Shiga toxin, Shiga like toxin I or Shiga like toxin II. Page 3, lines 12 and 18 mention that polyclonal antibodies which bind specifically to either Shiga toxin, Shiga like toxin I or Shiga like toxin II may be employed. Page 2, lines 6 and 7 states that Shiga like toxins are also referred to as verotoxins.

Page 7, line 35 to page 8, line 16 provides antecedent basis for <u>human</u> monoclonal antibodies and <u>human</u> nonspecific polyclonal antibodies as the antibodies that bind specifically to either Shiga toxin, Shiga like toxin I or Shiga like toxin II. Example 2 on pages 16 through 21 discloses the preparation of the human monoclonal antibodies using transgenic mice and the use of such human monoclonal antibodies to immunize mice.

Protester is including Attachment "A" which analyzes claim 22 of Applicants' WO 99/59629 against Protester's disclosure in WO 98/20903 to establish that Protester's

international application has antecedent basis to fully meet all of the subject matter of claim 22.

A copy of this protest has been served upon the Applicants at the address of their attorney stated on the cover page of WO 99/59629. The attorney listed is Joe Liebeschuetz, Townsend & Townsend, and Crew, LLP, 8th Floor, 2 Embarcadero Center, San Francisco, California 94111-3834.

Respectfully submitted,
The Firm of Karl F. Ross P.C.

Jonathan Myers, Reg. No. 26,963
Attorney for Applicant

er
13 September 2001
5676 Riverdale Avenue Box 900
Bronx, NY 10471-0900
Cust. No.: 535
Tel: (718) 884-6600
Fax: (718) 601-1099

Enclosures: Attachment "A"
WO 98/20903
WO 99/59629
Harold R..Brown III - Pages 77 - 107

Attachment "A"

Explanation of Pertinency and Manner of Applying WO 98/20903 Against Claim 22 of WO 99/59629

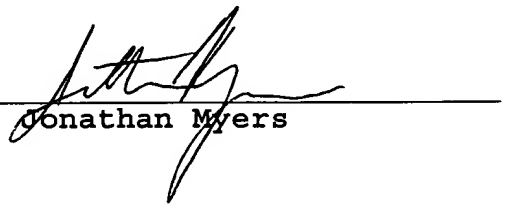
Claim 22 WO 99/59629	Specification WO 98/20903
"A method of treating a patient suffering or at risk of toxic effects from a verotoxin ...."	"A therapeutic method to treat hemolytic uremic syndrome ..." Page 2, lines 30 to 31.
	"The kidney damage and the neurological symptoms which are caused by one of 2 toxins is known as hemolytic uremic syndrome (HUS)" Page 1, lines 26 to 29.
	"The present invention is based, in one aspect, on the use of a therapeutic method to treat an individual suffering from hemolytic uremic syndrome (HUS) caused by a virulent strain at an Enterohemorragic E. Col. (EHEC)" Page 3, lines 23 to 26.
	"All EHEC produce toxins known as Shiga like toxins." Page 2, lines 5 and 6.
	"Shiga like toxins are also referred to as verotoxins" Page 2, lines 6 and 7.

"comprising administering to the patient"	"administering to an individual" Page 2, line 32.
"an effective dosage of a human or humanized antibody"	"a therapeutically effective amount of monoclonal antibody" Page 2, lines 32 and 33.
	"In one aspect of the present invention, human monoclonal and human mono-specific polyclonal antibodies are produced by using transgenic mice ..." Page 7, line 35 to page 8, line 1.
"that specifically binds to verotoxic II or verotoxin II variant".	"which binds specifically to either Shiga toxin, Shiga like toxin I or Shiga like toxin II." Page 2, lines 33 to 35.

D-850

CERTIFICATE OF SERVICE

It is hereby certified that a copy of this THIRD PARTY PROTEST BY THE PUBLIC AGAINST A PENDING PATENT APPLICATION was served by first class mail, postage prepaid, upon Applicants' attorney Joe Liebeschuetz, Esq., Townsend & Townsend and Crew, LLP, 8th Floor, 2 Embarcadero Center, San Francisco, California 94111-3834 on this 13th day of September 2001.



Jonathan Myers